Eric I. Abraham
Christina L. Saveriano
HILL WALLACK, LLP
21 Roszel Road
Princeton, NJ 08540
609-924-0808
eabraham@hillwallack.com
csaveriano@hillwallack.com

Attorneys for Defendants
Apotex Inc. and Apotex Corp.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI, Plaintiffs, v. APOTEX CORP. and APOTEX INC., Defendants.	)	Case No.: 3:15-cv-00287-MAS-LHG

DEFENDANTS APOTEX CORP. AND APOTEX INC.'S ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

Defendants Apotex Inc. and Apotex Corp. ("Defendants" or "Apotex"), by their undersigned counsel, for their Answer to the Complaint filed by Sanofi-Aventis U.S. LLC, Aventis Pharma S.A. and Sanofi ("Plaintiffs"), state as follows:

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b) (3), Apotex denies all allegations in Plaintiffs' Complaint except those specifically admitted below:

THE PARTIES

1. Plaintiff Sanofi U.S. is a U.S. subsidiary of Sanofi and is a company organized and existing under the laws of the State of Delaware, having commercial headquarters at 55 Corporate Drive, Bridgewater, New Jersey 08807.

ANSWER: Apotex lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 1, and on that basis denies these allegations.

2. Plaintiff Aventis is a corporation organized and existing under the laws of France, having its principal place of business at 20 Avenue Raymond Aron, 92160 Antony, France.

ANSWER: Apotex lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 2, and on that basis denies these allegations.

3. Plaintiff Sanofi is a corporation organized and existing under the laws of France, having its principal place of business at 54 rue La Boétie, 75008 Paris, France.

ANSWER: Apotex lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 3, and on that basis denies these allegations.

4. Plaintiff Sanofi is a global research-driven pharmaceutical company that discovers, develops, manufactures and markets a broad range of innovative products to improve human and animal health.

ANSWER: Apotex lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 4, and on that basis denies these allegations.

5. On information and belief, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

ANSWER: Apotex admits the allegations of Paragraph 5.

6. On information and belief, Apotex Inc. is a corporation organized and existing under the laws of Canada, having its principal place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L IT9.

ANSWER: Apotex admits the allegations of Paragraph 6.

7. On information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Inc.

ANSWER: Paragraph 7 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex Corp. admits that it is a subsidiary of Apotex Inc., and denies the remaining allegations of Paragraph 7.

8. On information and belief, Apotex Inc. assembled and caused to be filed with the United States Food and Drug Administration ("FDA"), pursuant to 21 U.S.C. § 355(j) (Section 505(j) of the Federal Food, Drug and Cosmetic Act), Abbreviated New Drug Application ("ANDA") No. 207736 (hereinafter "the Apotex ANDA") concerning a proposed drug product, Cabazitaxel Injection, 60 mg/1.5 mL ("Apotex's Proposed ANDA Product").

ANSWER: Apotex admits that it filed ANDA No. 207736 with the FDA pursuant to 21 U.S.C. § 355(j) *et seq.* concerning cabazitaxel injection, 60 mg/1.5 mL. Apotex denies any remaining allegations of Paragraph 8.

JURISDICTION AND VENUE

9. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Paragraph 9 contains legal conclusions to which no answer is required. To the extent, if any, Apotex is required to answer, Apotex admits that subject matter jurisdiction is proper, if at all, solely for Plaintiffs' infringement claims against Apotex under 35 U.S.C. § 271(e)(2)(A). Apotex denies that subject matter jurisdiction is proper for any claims asserted

against Apotex under 35 U.S.C. §§ 271(a)-(c). Apotex denies any and all remaining allegations of Paragraph 9.

10. This Court has personal jurisdiction over Apotex Corp. Apotex Corp. directly or through its subsidiaries, affiliates and agents develops, formulates, manufactures, markets, imports and sells pharmaceutical products, including generic drug products, which are copies of products invented and developed by innovator pharmaceutical companies, throughout the United States, including in this Judicial District. On information and belief, Apotex Corp. holds an active wholesale drug license for the State of New Jersey under License No. 5003192.

ANSWER: Paragraph 10 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this Judicial District for the limited purposes of this action only. Further answering, Apotex admits that its business includes developing and selling quality pharmaceutical products, including generic drug products. All other allegations are denied.

11. On information and belief, Apotex Corp. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. On information and belief, Apotex Corp. "has successfully secured FDA approval for over 230 ANDAs" and "boast[s] over a billion dollars in sales and a new ranking in the top 10 generic pharmaceutical companies according to recent IMS HEALTH data." *Apotex Corp: A Global Leader Focused on Excellence*, Pharmacy Times available at http://www.pharmacytimes.com/publications/supplement/2013/Generic-Supplement- 2013/Apotex-Corp-A-Global-Leader-Focused-on-Excellence. (last visited January 6, 2015).

ANSWER: Apotex admits that its business includes developing and selling quality pharmaceutical products, including generic drug products. Apotex denies all remaining allegations of Paragraph 11.

12. On information and belief, Apotex Corp. has affiliations with the State of New Jersey that are pervasive, continuous, and systematic. On information and belief,

Apotex Corp. engages in direct marketing, distribution, and/or sale of generic pharmaceutical drugs within the State of New Jersey and to the residents of the State of New Jersey.

ANSWER: Paragraph 12 contains legal conclusions and allegations to which no answer is required. Apotex Corp. notes that solely to conserve the resources of the parties and the Court, Apotex Corp. does not contest personal jurisdiction in this Judicial District for the limited purposes of this action only. To the extent an answer is required, all other allegations are denied.

13. On information and belief, Apotex Corp. regularly conducts and/or solicits business in the State of New Jersey, engages in other persistent courses of conduct in the State of New Jersey, and/or derives substantial revenue from services or things used or consumed in the State of New Jersey.

ANSWER: Paragraph 13 contains legal conclusions and allegations to which no answer is required. Apotex Corp. notes that solely to conserve the resources of the parties and the Court, Apotex Corp. does not contest personal jurisdiction in this Judicial District for the limited purposes of this action only. To the extent an answer is required, all other allegations are denied.

14. On information and belief, Apotex Corp. has previously submitted to the jurisdiction of this Court and have availed themselves of the legal protections of the State of Delaware, having asserted counterclaims in this jurisdiction, including in the matters of *Novartis Pharmaceuticals Corporation v. Apotex Inc. et al.*, Civil Action No. 2:12-cv-05574 (JLL) (MAH), D.I. 12 at 2-3, 10-12 (D.N.J. Feb. 11, 2013); *Otsuka Pharmaceutical Co., Ltd. v. Apotex Corp. et al.*, Civil Action No. 3:12-cv-05645 (MLC) (LHG), D.I. 27 at 3-5, 15-20 (D.N.J. Dec. 11, 2012); *Actelion Pharmaceuticals Ltd. et al. v. Apotex Inc. et al.*, Civil Action No. 1:12-cv-05743 (NLH) (AMD), D.I. 24 at 13-33 (D.N.J. Nov. 27, 2012); and *Hoffman-La Roche, Inc. v. Apotex Inc. et al.*, Civil Action No. 2:10-cv-06241 (SRC) (MAS), D.I. 14 at 3-4, 20-24 (D.N.J. Jan. 12, 2011).

ANSWER: Paragraph 14 contains legal conclusions and allegations to which no answer is required. Apotex Corp. notes that solely to conserve the resources of the parties and the Court, Apotex Corp. does not contest personal jurisdiction in this Judicial District for the limited purposes of this action only. To the extent an answer is required, all other allegations are denied.

15. On information and belief, upon approval of the Apotex ANDA, Apotex Corp. and/or its subsidiaries, affiliates or agents will market, sell and/or distribute Apotex's Proposed ANDA Product throughout the United States, including in this Judicial District, and will derive substantial revenue therefrom.

ANSWER: Paragraph 15 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations.

16. On information and belief, upon approval of the Apotex ANDA, Apotex Corp. and/or its subsidiaries, affiliates or agents will place Apotex's Proposed ANDA Product into the stream of commerce with the reasonable expectation or knowledge and the intent that such product will ultimately be purchased and used by consumers in this Judicial District.

ANSWER: Paragraph 16 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations.

17. This Court has personal jurisdiction over Apotex Inc. On information and belief, Apotex Inc. directly or through its subsidiaries, affiliates and agents develops, formulates, manufactures, markets, imports and sells pharmaceutical products, including generic drug products, which are copies of products invented and developed by innovator pharmaceutical companies, throughout the United States, including in this Judicial District. On information and belief, Apotex Inc. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products.

ANSWER: Paragraph 17 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that its business includes developing and manufacturing pharmaceuticals, including quality generic drug products. Further answering, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this Judicial District for the limited purposes of this action only. All other remaining allegations are denied.

18. On information and belief, Apotex Inc. has affiliations with the State of New Jersey that are pervasive, continuous, and systematic. On information and belief, Apotex Inc. engages in direct marketing, distribution, and/or sale of generic

pharmaceutical drugs within the State of New Jersey and to the residents of the State of New Jersey.

ANSWER: Paragraph 18 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies all allegations of Paragraph 18.

19. On information and belief, Apotex Inc. regularly conducts and/or solicits business in the State of New Jersey, engages in other persistent courses of conduct in the State of New Jersey, and/or derives substantial revenue from services or things used or consumed in the State of New Jersey.

ANSWER: Paragraph 19 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies all allegations of Paragraph 19.

20. On information and belief, Apotex Inc. has previously submitted to the jurisdiction of this Court and have availed themselves of the legal protections of the State of New Jersey, having asserted counterclaims in this jurisdiction, including in the matters of *Novartis Pharmaceuticals Corporation v. Apotex Inc. et al.*, Civil Action No. 2:12-cv-05574 (JLL) (MAH), D.I. 12 at 2-3, 10-12 (D.N.J. Feb. 11, 2013); *Otsuka Pharmaceutical Co., Ltd. v. Apotex Corp. et al.*, Civil Action No. 3:12-cv-05645 (MLC) (LHG), D.I. 27 at 3-5, 15-20 (D.N.J. Dec. 11, 2012); *Actelion Pharmaceuticals Ltd. et al. v. Apotex Inc. et al.*, Civil Action No. 1:12-cv-05743 (NLH) (AMD), D.I. 24 at 13-33 (D.N.J. Nov. 27, 2012); and *Hoffman-La Roche, Inc. v. Apotex Inc. et al.*, Civil Action No. 2:10-cv-06241 (SRC) (MAS), D.I. 14 at 3-4, 20-24 (D.N.J. Jan. 12, 2011).

ANSWER: Paragraph 21 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex does not contest personal jurisdiction in this District for the purposes of this action only. Apotex denies all remaining allegations of Paragraph 20.

21. Apotex Inc. is also subject to personal jurisdiction in the State of New Jersey because, *inter alia*, Apotex Inc. has committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under

35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Plaintiff Sanofi U.S., having commercial headquarters in the State of New Jersey. Apotex Inc. sent its December 4, 2014 Paragraph IV Notice Letter to Sanofi U.S.'s commercial headquarters at 55 Corporate Drive, Bridgewater, New Jersey, 08807. Plaintiff's cause of action arose from Apotex Inc.'s contact with Sanofi U.S. in Bridgewater, New Jersey. Apotex Inc. states that it intends to engage in the commercial manufacture, use, and/or sale of Apotex Inc.'s Proposed ANDA Product before the expiration of U.S Patent Nos. 5,847,170 ("'170 patent") and 7,241,907 ("'907 patent") throughout the United States, including in this Judicial District.

ANSWER: Paragraph 21 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex does not contest personal jurisdiction in this District for the purposes of this action only. Further answering, Apotex admits that it sent a letter dated December 4, 2014, to Sanofi, which served as written notifications pursuant to 21 U.S.C. § 355(j)(2)(B) of Apotex's ANDA and Paragraph IV Certification as to the '170 patent and the '907 patent, and which satisfied all statutory, legal, and regulatory requirements. Any and all other remaining allegations of Paragraph 21 are denied.

22. In the alternative, Apotex Inc. is subject to jurisdiction in the United States under the principles of general jurisdiction, and specially in the State of New Jersey pursuant to Fed. R. Civ. P. 4(k)(2). Apotex Inc. has contacts with the United States by, *inter alia*, its having filed an ANDA with the FDA.

ANSWER: Paragraph 22 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits it filed an ANDA with the FDA. Apotex denies all remaining allegations of paragraph 22.

23. On information and belief, upon approval of the Apotex ANDA, Apotex Inc. and/or its subsidiaries, affiliates or agents will market, sell and/or distribute Apotex's Proposed ANDA Product throughout the United States, including in this Judicial District, and will derive substantial revenue therefrom.

ANSWER: Paragraph 23 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies all allegations of Paragraph 19.

24. On information and belief, upon approval of the Apotex ANDA, Apotex Inc. and/or its subsidiaries, affiliates or agents will place Apotex's Proposed ANDA Product into the stream of commerce with the reasonable expectation or knowledge and the intent that such product will ultimately be purchased and used by consumers in this Judicial District.

ANSWER: Paragraph 24 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies all allegations of Paragraph 24.

25. Venue is proper in this Court at least pursuant to 28 U.S.C. §§ 1391(b), (c), and/or (d), and 1400(b).

ANSWER: Paragraph 25 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex will not contest venue for the purposes of this action only. Apotex denies all remaining allegations of paragraph 25.

THE PATENTS-IN-SUIT

26. Sanofi U.S. holds approved New Drug Application ("NDA") No. 201023 for cabazitaxel injection, 60 mg/ 1.5 mL (40 mg/mL), which is prescribed and sold in the United States under the trademark JEVTANA® KIT (hereinafter "JEVTANA®"). The U.S. Food and Drug Administration ("FDA") approved NDA No. 201023 on June 17, 2010. JEVTANA® is approved for use in combination with prednisone for the treatment of patients with hormone- refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen.

ANSWER: Apotex admits that the FDA's electronic Orange Book lists Sanofi Aventis U.S. as the holder of NDA No. 201023 for cabazitaxel solution and/or IV (infusion), 60 mg/ 1.5 mL (40 mg/mL), which is sold in the United States under the brand name JEVTANA® KIT.

Apotex admits the FDA approved NDA No. 201023 on June 17, 2010. Apotex lacks knowledge or information sufficient to form a belief as to the truth of all remaining allegations of Paragraph 26, and therefore denies these allegations.

27. United States Patent No. 5,847,170 (the "'170 patent," copy attached as Exhibit A) is entitled "Taxoids, Their Preparation And Pharmaceutical Compositions Containing Them" and was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on December 8, 1998. The '170 patent claims, *inter alia*, cabazitaxel and pharmaceutical compositions containing cabazitaxel. The '170 patent is listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for JEVTANA® (NDA No. 201023).

ANSWER: Apotex admits that the '170 patent is entitled "Taxoids, Their Preparation And Pharmaceutical Compositions Containing Them," and bears an issue date of December 8, 1998, but denies that the '170 patent was duly and legally issued, and further denies any suggestion that the '170 patent is valid or enforceable. Further answering, Apotex admits the '170 patent is listed in the Orange Book for NDA No. 201023. Apotex lacks knowledge or information sufficient to form a belief as to the truth of all remaining allegations of Paragraph 27, and on that basis, denies all remaining allegations.

28. The '170 patent is owned by Aventis.

ANSWER: Apotex lacks knowledge or information sufficient to form a belief as to the truth of all allegations of Paragraph 28, and on that basis, denies these allegations.

29. United States Patent No. 7,241,907 (the "'907 patent," copy attached as Exhibit B) is entitled "Acetone Solvate of Dimethoxy Docetaxel and its Process of Preparation" and was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on July 10, 2007. The '907 patent claims, *inter alia*, an acetone solvate of cabazitaxel. The '907 patent is listed in the FDA's Orange Book for JEVTANA® (NDA No. 201023).

ANSWER: Paragraph 29 contains legal conclusions to which no answer is required. To the extent Apotex is required to answer, Apotex admits that the '907 patent is entitled "Acetone Solvate of Dimethoxy Docetaxel and its Process of Preparation," and bears an issue date of July 10, 2007, but denies that the '907 patent was duly and legally issued, and further denies any suggestion that the '907 patent is valid or enforceable. Further answering, Apotex admits the '907 patent is listed in the electronic Orange Book for NDA No. 201023. Apotex lacks knowledge or information sufficient to form a belief as to the truth of all remaining allegations of Paragraph 29, and on that basis, denies all remaining allegations.

30. The '907 patent is owned by Aventis.

ANSWER: Apotex lacks knowledge or information sufficient to form a belief as to the truth of all allegations of Paragraph 30, and on that basis, denies these allegations.

CLAIMS FOR RELIEF PATENT INFRINGEMENT

31. On information and belief, Apotex Inc. submitted the Apotex ANDA to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's Proposed ANDA Product.

ANSWER: Paragraph 31 contains legal conclusions to which no answer is required. To the extent Apotex is required to answer, Apotex admits that it submitted an ANDA to the FDA seeking approval for cabazitaxel injection, 60 mg/1.5 mL. Apotex denies any and all remaining allegations of Paragraph 31.

32. On information and belief, the Apotex ANDA seeks FDA approval of Apotex's Proposed ANDA Product for use in combination with prednisone for the treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen.

ANSWER: Paragraph 32 contains legal conclusions to which no answer is required. To the extent Apotex is required to answer, Apotex admits that it submitted an ANDA to the FDA seeking approval for cabazitaxel injection, 60 mg/1.5 mL. Apotex denies any and all remaining allegations of Paragraph 32.

33. On information and belief, Apotex Inc. actively collaborated with Apotex Corp. and/or participated in and/or directed activities related to the submission of the Apotex ANDA and the development of Apotex's Proposed ANDA Product, was actively involved in preparing the ANDA, and/or intends to directly benefit from and has a financial stake in the approval of the ANDA. On information and belief, upon approval of the Apotex ANDA, Apotex Inc. will be involved in the manufacture, distribution, and/or marketing of Apotex's Proposed ANDA Product.

ANSWER: Paragraph 33 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that it submitted an ANDA to the FDA seeking approval for cabazitaxel injection, 60 mg/1.5 mL. Apotex denies the remaining allegations of Paragraph 33.

34. On information and belief, Apotex Corp. actively collaborated with Apotex Inc. and/or participated in and/or directed activities related to the submission of the Apotex ANDA and the development of Apotex's Proposed ANDA Product, was actively involved in preparing the ANDA, and/or intends to directly benefit from and has a financial stake in the approval of the ANDA. On information and belief, upon approval of the Apotex ANDA, Apotex Corp. will be involved in the manufacture, distribution, and/or marketing of Apotex's Proposed ANDA Product.

ANSWER: Paragraph 34 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that it submitted an ANDA to the FDA seeking approval for cabazitaxel injection, 60 mg/1.5 mL. Apotex denies the remaining allegations of Paragraph 34.

35. By letter dated December 4, 2014 (the "December 4 Letter"), and pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. §314.95, Apotex Inc. notified Plaintiffs that it had submitted to the FDA the Apotex ANDA, seeking approval to engage in the commercial manufacture, use, or sale of Apotex's Proposed ANDA Product before the expiration of the '170 patent and the '907 patent. The December 4 Letter was received by Plaintiffs on December 5, 2014.

ANSWER: Paragraph 35 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that it sent a letter dated December 4, 2014, to Sanofi, which served as written notification pursuant to 21 U.S.C. § 355(j)(2)(B) of Apotex's ANDA and Paragraph IV Certifications as to the '170 patent and the '907 patent, and which satisfied all statutory, legal, and regulatory requirements. Any and all other remaining allegations of Paragraph 35 are denied.

36. In its December 4 Letter, Apotex Inc. notified Plaintiffs, as part of the Apotex ANDA, it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification") with respect to the '170 patent and the '907 patent. On information and belief, Apotex Inc. certified that, the '170 patent and the '907 patent are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of Apotex's Proposed ANDA Product.

ANSWER: Paragraph 36 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that it sent a letter dated December 4, 2014, to Sanofi, which served as written notification pursuant to 21 U.S.C. § 355(j)(2)(B) of Apotex's ANDA and Paragraph IV Certifications as to the '170 patent and the '907 patent, and which satisfied all statutory, legal, and regulatory requirements. Any and all other remaining allegations of Paragraph 36 are denied.

37. The Apotex ANDA refers to and relies upon the Sanofi U.S.'s NDA No. 201023 for JEVTANA®.

ANSWER: The contents of the Apotex ANDA speak for itself. To the extent an answer is required, Apotex admits that NDA 201023 is the Reference Listed Drug identified in Apotex's ANDA. All remaining allegations are denied.

38. In the December 4 Letter, Apotex offered confidential access to portions of the Apotex ANDA on terms and conditions set forth in paragraph 2 of the December 4 Letter ("Apotex Offer"). Apotex requested that Plaintiffs accept the Apotex Offer before receiving access to any portion of the Apotex ANDA. The Apotex Offer contained unreasonable restrictions that would apply under a protective order. For example, the Apotex Offer required that Plaintiffs' outside counsel do not engage, formally or informally, in any patent prosecution or any FDA counseling, litigation or other work before or involving the FDA on behalf of Plaintiffs.

ANSWER: Paragraph 38 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that it sent a letter dated December 4, 2014, to Sanofi, which served as written notification pursuant to 21 U.S.C. § 355(j)(2)(B) of Apotex's ANDA and Paragraph IV Certifications as to the '170 patent and the '907 patent, which included an offer for confidential access, and which satisfied all statutory, legal, and regulatory requirements. Any and all other remaining allegations of Paragraph 38 are denied.

39. Under 21 U.S.C. § 355(j)(5)(C)(i)(III), an "offer of confidential access shall contain such restrictions . . . on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information."

ANSWER: Paragraph 39 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 39.

40. Since rejecting the Apotex Offer, Plaintiffs attempted to negotiate with Apotex to obtain a copy of excerpts of the Apotex ANDA under restrictions "as would apply had a protective order been issued." Those negotiations were unsuccessful. For example, Apotex's final proposal continued to unreasonably impose patent prosecution and FDA restrictions on Plaintiffs' outside counsel.

ANSWER: Paragraph 40 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that it offered confidential access to its ANDA under reasonable restrictions as permitted by 21 U.S.C. § 355(j)(5)(C)(i)(III), which Plaintiffs rejected. Any remaining allegations are denied.

41. Plaintiffs are not aware of any other means of obtaining information regarding Apotex's Proposed ANDA Product within the 45-day statutory period. Without such information, Plaintiffs will use the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards such information as is required to confirm its allegations of infringement and to present to the Court evidence that Apotex's Proposed ANDA Product falls within the scope of one or more claims of the '170 and '907 patents.

ANSWER: Paragraph 41 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 41.

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 5,847,170

42. Plaintiff repeats and realleges paragraphs 1 through 41 above as if fully set forth herein.

ANSWER: Apotex incorporates its answers to Paragraphs 1 through 41 as if fully set forth herein.

43. By submitting the Apotex ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of Apotex's Proposed ANDA Product throughout the United States prior to the expiration of the '170 patent, Defendants committed an act of infringement of the

'170 patent under 35 U.S.C. § 271(e)(2). On information and belief, Defendants were aware of the '170 patent at the time the Apotex ANDA was submitted.

ANSWER: Paragraph 43 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that filed an ANDA with FDA, which contained a Paragraph IV Certification to the '170 patent, which satisfied all statutory, legal, and regulatory requirements. Any and all other remaining allegations of Paragraph 43 are denied.

44. If Defendants commercially make, use, offer to sell, or sell Apotex's Proposed ANDA Product within the United States, or import Apotex's Proposed ANDA Product into the United States, or induce or contribute to any such conduct during the term of the '170 patent, they would further infringe the '170 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Paragraph 44 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 44.

45. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '170 patent. Plaintiffs do not have an adequate remedy at law.

ANSWER: Paragraph 45 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 45.

46. Apotex Inc.'s certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '170 patent was wholly unjustified, and thus this case is exceptional under 35 U.S.C. § 285.

ANSWER: Paragraph 46 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 46.

COUNT II

INFRINGEMENT OF U.S. PATENT NO. 7,241,907

47. Plaintiffs repeat and reallege paragraphs 1 through 46 above as if fully set forth herein.

ANSWER: Apotex incorporates its answers to Paragraphs 1 through 46 as if fully set forth herein.

48. By submitting the Apotex ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of Apotex's Proposed ANDA Product throughout the United States prior to the expiration of the '907 patent, Defendants committed an act of infringement of the '907 patent under 35 U.S.C. § 271(e)(2). On information and belief, Defendants were aware of the '907 patent at the time the Apotex ANDA was submitted.

ANSWER: Paragraph 48 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that it filed an ANDA with FDA, which contained a Paragraph IV Certification to the '907 patent, which satisfied all statutory, legal, and regulatory requirements. Any and all other remaining allegations of Paragraph 48 are denied.

49. If Defendants commercially make, use, offer to sell, or sell Apotex's Proposed ANDA Product within the United States, or import Apotex's Proposed ANDA Product into the United States, or induce or contribute to any such conduct during the term of the '907 patent, it would further infringe the '907 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Paragraph 49 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 49.

50. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '907 patent. Plaintiffs do not have an adequate remedy at law.

ANSWER: Paragraph 50 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 50.

51. Apotex Inc.'s certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '907 patent was wholly unjustified, and thus this case is exceptional under 35 U.S.C. § 285.

ANSWER: Paragraph 51 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of Paragraph 51.

PRAYER FOR RELIEF

Plaintiffs request that:

A. A judgment that Defendants have infringed one or more claims of the '170 patent by filing ANDA No. 207736 relating to Apotex's Proposed ANDA Product before the expiration of the '170 patent;

B. A judgment that the manufacture, use, offer for sale, sale and/or importation of Apotex's Proposed ANDA Product will infringe the '170 patent;

C. A judgment declaring that the '170 patent remains valid and enforceable;

D. A permanent injunction restraining and enjoining Defendants, and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Apotex's Proposed ANDA Product until the expiration of the '170 patent or any later date of exclusivity to which Plaintiffs and/or the '170 patent are or become entitled to;

E. An order that the effective date of any approval of Apotex's ANDA No. 207736 relating to Apotex's Proposed ANDA Product under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration date of the '170 patent or any later date of exclusivity to which Plaintiffs and/or the '170 patent are or become entitled;

F. A judgment that Defendants have infringed one or more claims of the '907 patent by filing ANDA No. 207736 relating to Apotex's Proposed ANDA Product before the expiration of the '907 patent;

G. A judgment that the manufacture, use, offer for sale, sale and/or importation of Apotex's Proposed ANDA Product will infringe the '907 patent;

H. A judgment declaring that the '907 patent remains valid and enforceable;

I. A permanent injunction restraining and enjoining Defendants, and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Apotex's Proposed ANDA Product until the expiration of the '907 patent or any later date of exclusivity to which Plaintiffs and/or the '907 patent are or become entitled to;

J. An order that the effective date of any approval of Apotex's ANDA No. 207736 relating to Apotex's Proposed ANDA Product under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration date of the '907 patent or any later date of exclusivity to which Plaintiffs and/or the '907 patent are or become entitled;

K. A declaration that this case is "exceptional" within the meaning of 35 U.S.C. § 285 and an award of reasonable attorney fees, costs, expenses, and disbursements of this action; and

L. Such other and further relief as the Court may deem just and proper.

ANSWER: Apotex denies Plaintiffs are entitled to any of the relief requested in their Prayer for Relief.

APOTEX'S ADDITIONAL DEFENSES

Apotex asserts the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted.

FIRST AFFIRMATIVE DEFENSE
(INVALIDITY)

The claims of the '170 patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq*. including, *inter alia*, §§ 102, 103, and/or 112, or under other judicially-created bases for invalidation.

SECOND AFFIRMATIVE DEFENSE
(INVALIDITY)

The claims of the '907 patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq*. including, *inter alia*, §§ 102, 103, and/or 112, or under other judicially-created bases for invalidation.

THIRD AFFIRMATIVE DEFENSE
(NO DIRECT INFRINGEMENT)

The manufacture, use, offer for sale, sale, or importation of Apotex's ANDA Products specified in ANDA No. 207736 does not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '170 patent.

FOURTH AFFIRMATIVE DEFENSE
(NO INDIRECT INFRINGEMENT)

The manufacture, use, offer for sale, sale, or importation of Apotex's ANDA Products specified in ANDA No. 207736 does not and will not induce the infringement of, and has not, does not, and will not contribute to the infringement of any valid and enforceable claim of the '170 patent.

FIFTH AFFIRMATIVE DEFENSE
(NO DIRECT INFRINGEMENT)

The manufacture, use, offer for sale, sale, or importation of Apotex's ANDA Products specified in ANDA No. 207736 does not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '907 patent.

SIXTH AFFIRMATIVE DEFENSE
(NO INDIRECT INFRINGEMENT)

The manufacture, use, offer for sale, sale, or importation of Apotex's ANDA Products specified in ANDA No. 207736 does not and will not induce the infringement of, and has not, does not, and will not contribute to the infringement of any valid and enforceable claim of the '907 patent.

SEVENTH AFFIRMATIVE DEFENSE
(FAILURE TO STATE A CLAIM)

Plaintiffs' complaint, in whole and/or in part, fails to state a claim upon which relief can be granted.

EIGHTH AFFIRMATIVE DEFENSE

Plaintiffs' Complaint lacks subject matter jurisdiction over any and all claims asserted under 35 U.S.C. § 271(a), (b), and/or (c).

NINTH AFFIRMATIVE DEFENSE

Plaintiffs' fail to state a proper claim for an exceptional case and/or willful infringement.

RESERVATION OF ADDITIONAL AFFIRMATIVE DEFENSES

Apotex reserves the right to plead additional affirmative defenses or counterclaims that may be revealed through the course of discovery, including unenforceability.

COUNTER CLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Apotex Inc. and Apotex Corp. (collectively "Apotex"), by way of its attorneys, hereby state for their Counterclaims against Plaintiffs'/Counterclaim-Defendants Sanofi-Aventis U.S. LLC, Aventis Pharma S.A., and Sanofi (collectively "Sanofi-Aventis" or "Plaintiffs/Counterclaim-Defendants"), the following:

THE PARTIES

1. Apotex repeats and incorporates by reference each of the foregoing paragraphs of Apotex's Answer and Affirmative Defenses to the Complaint.

2. This is an action for a declaratory judgment of non-infringement and invalidity of one or more claims of United States Patent No. 5,847,170 ("the '170 Patent"), as well as one or more claims of United States Patent No. 7,241,907 ("the '907 Patent"). Upon information and belief a true and correct copy of the '170 Patent was attached to the Complaint as Exhibit A, and a true and correct copy of the '907 Patent was attached as Exhibit B.

3. Apotex Inc. is a corporation organized and existing under the laws of Canada, with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

4. Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 2400 North Commerce Parkway, Suite 400, Weston Florida, 33326.

5. Upon information and belief, Plaintiff/Counterclaim-Defendant Sanofi-Aventis U.S. is a wholly owned subsidiary of Sanofi and is a company organized and existing under the laws of the State of Delaware, having commercial headquarters at 55 Corporate Drive, Bridgewater, New Jersey 08807.

6. Upon information and belief, Plaintiff/Counterclaim-Defendant Aventis Pharma S.A. is a corporation organized and existing under the laws of France, having its principal place of business at 20 avenue Raymond Aron, 92160 Antony, France.

7. Upon information and belief, Plaintiff/Counterclaim-Defendant Sanofi is a corporation organized and existing under the laws of France, having its principal place of business at 54 rue La Boétie, 75008 Paris, France.

JURISDICTION

8. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

9. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

10. This court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202, based on an actual controversy between Apotex, and Plaintiffs/Counterclaim-Defendants, arising under the Patent Laws of the United States, 35 U.S.C. § 1 et seq.

11. This court has personal jurisdiction over Plaintiffs/Counterclaim-Defendants based, *inter alia*, on the filing of this lawsuit in this jurisdiction and because Counterclaim-Defendants are doing business in this jurisdiction.

12. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

FACTS COMMON TO ALL COUNTS

13. On or about December 8, 1998 the U.S. Patent & Trademark Office ("PTO") issued the '170 Patent.

14. Upon information and belief, Plaintiff/Counterclaim-Defendant Aventis Pharma S.A. is the owner of the '170 Patent.

15. On or about July 10, 2007, the PTO issued the '907 Patent.

16. Upon information and belief, Plaintiff/Counterclaim-Defendant Aventis Pharma S.A. is the owner of the '907 Patent.

17. Plaintiff/Counterclaim-Defendant Sanofi-Aventis U.S. purports to be the holder of approved New Drug Application ("NDA") No. 201023 for cabazitaxel injection, 60 mg/ 1.5 mL (40 ms/mL), which is prescribed and sold in the United States under trademark JEVTANA® KIT ("JEVTANA®"). On or about June 17, 2010, the U.S. Food & Drug Administration ("FDA") approved NDA No. 201023.

18. Plaintiffs/Counterclaim-Defendants purport and claim to have the right to enforce the '170 Patent and the '907 Patent, and have listed both patents in the FDA's "Approved Drug Products and Therapeutic Equivalence Evaluations" (the "Orange Book") for JEVTANA®.

19. By listing the '170 Patent and '907 Patent in the Orange Book, Plaintiffs/Counterclaim-Defendants maintain that an infringement suit could be reasonably asserted against any sponsor of an Abbreviated New Drug Application ("ANDA"), including Apotex, that attempts to seek approval for, and market, a generic version of JEVTANA® before expiration of the patents.

20. Apotex has filed an ANDA with the FDA seeking approval for cabazitaxel injection, 60 mg/1.5 mL, identifying NDA 201023 as the Reference Listed Drug pursuant to 21 C.F.R. § 314.3.

21. Because Apotex's ANDA seeks FDA approval to market the cabazitaxel injection, 60 mg/1.5 mL product described within it before the expiration of the '170 Patent and '907 Patent listed in the Orange Book, Apotex's ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (also called a "Paragraph IV Certification") to the '170 Patent and '907 Patent.

22. Plaintiffs/Counterclaim-Defendants sued Apotex in this District for alleged infringement of both the '170 Patent and '907 Patent.

COUNT I

Declaratory Judgment of Invalidity of the 170 Patent

23. Apotex realleges and incorporates by reference the allegations of paragraphs 1-22 as though fully set forth herein.

24. There is an actual, substantial, and continuing case or controversy between Apotex and the Counterclaim-Defendants regarding, *inter alia*, the invalidity of the '170 Patent.

25. The claims of the '170 Patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, including but not limited, to 35 U.S.C. §§ 102, 103, and/or 112.

26. Apotex is entitled to a judicial declaration that the claims of the '170 Patent are invalid.

COUNT II

Declaratory Judgment of Non-Infringement of the '170 Patent

27. Apotex realleges and incorporates by reference the allegations of paragraphs 1-22 as though fully set forth herein.

28. There is an actual, substantial, and continuing case or controversy between Apotex and the Counterclaim-Defendants regarding, inter alia, non-infringement of the claims of the '170 Patent.

29. The manufacture, use, offer for sale, sale, importation, and/or marketing of the cabazitaxel injection, 60 mg/1.5 mL product described in Apotex's ANDA has not infringed, does not infringe, and would not —if made, used, sold, offered for sale, imported or marketed— infringe, either directly or indirectly, any valid or enforceable claim of the '170 Patent, either literally or under the doctrine of equivalents.

30. Apotex is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of the cabazitaxel injection, 60 mg/1.5 mL product described in Apotex's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '170 Patent, either literally or under the doctrine of equivalents.

COUNT III

Declaratory Judgment of Invalidity of the '907 Patent

31. Apotex realleges and incorporates by reference the allegations of paragraphs 1-22 as though fully set forth herein.

32. There is an actual, substantial, and continuing case or controversy between Apotex and the Counterclaim-Defendants regarding, *inter alia*, the invalidity of the '907 Patent.

33. The claims of the '907 Patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, including but not limited, to 35 U.S.C. §§ 102, 103, and/or 112.

34. Apotex is entitled to a judicial declaration that the claims of the '907 Patent are invalid.

COUNT IV

Declaratory Judgment of Non-Infringement of the '907 Patent

35. Apotex realleges and incorporates by reference the allegations of paragraphs 1-22 as though fully set forth herein.

36. There is an actual, substantial, and continuing case or controversy between Apotex and the Counterclaim-Defendants regarding, inter alia, non-infringement of the claims of the '907 Patent.

37. The manufacture, use, offer for sale, sale, importation, and/or marketing of the cabazitaxel injection, 60 mg/1.5 mL product described in Apotex's ANDA has not infringed, does not infringe, and would not —if made, used, sold, offered for sale, imported or marketed— infringe, either directly or indirectly, any valid or enforceable claim of the '907 Patent, either literally or under the doctrine of equivalents.

38. Apotex is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of the cabazitaxel injection, 60 mg/1.5 mL product described in Apotex's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '907 Patent, either literally or under the doctrine of equivalents.

PRAYER FOR RELIEF

WHEREFORE, Apotex Inc. and Apotex Corp. respectfully pray for judgment in their favor and against Plaintiffs/Counterclaim-Defendants:

A. Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of the cabazitaxel injection, 60 mg/1.5 mL product described in Apotex's ANDA 207736 has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any valid and/or enforceable claim of the '170 Patent, either literally or under the doctrine of equivalents;

B. Declaring that the claims of the '170 Patent are invalid;

C. Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of the cabazitaxel injection, 60 mg/1.5 mL product described in Apotex's ANDA 207736 has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any valid and/or enforceable claim of the '907 Patent, either literally or under the doctrine of equivalents;

D. Declaring that the claims of the '907 Patent are invalid;

E. Ordering that Plaintiffs'/Counterclaim-Defendants' Complaint be dismissed with prejudice and judgment entered in favor of Apotex Inc. and Apotex Corp.;

F. Declaring this case exceptional and awarding Apotex Inc. and Apotex Corp. their reasonable attorneys' fees and costs of these Counterclaims under 35 U.S.C. § 285;

G. Ordering that Plaintiffs/Counterclaim-Defendants, and their officers, agents, servants, employees, attorneys, successors and any person who acts in concert or participation with

them, be preliminarily and permanently enjoined from using the '170 Patent or '907 Patent to block, hamper, hinder or obstruct FDA approval of the products described in Apotex's ANDA; and

Awarding such other and further relief as the Court may deem just and proper.

Dated: March 20, 2015

s/ Eric I. Abraham
Eric I. Abraham
Christina L. Saveriano
HILL WALLACK, LLP
21 Roszel Road
Princeton, NJ 08540
609-924-0808
eabraham@hillwallack.com
csaveriano@hillwallack.com

Of Counsel:

Stephen R. Auten
Richard T. Ruzich
Roger Kiley
TAFT STETTINIUS & HOLLISTER LLP
111 East Wacker Drive
Suite 2800
Chicago, IL 60601
312-527-4000
sauten@taftlaw.com
rruzich@taftlaw.com
rkiley@taftlaw.com

Attorneys for Defendants
Apotex Inc. and Apotex Corp.

LOCAL CIVIL RULE 11.2 CERTIFICATION

I hereby certify pursuant to Local Civil Rule 11.2, that to the best of my knowledge, information and belief the patents at issue in this action are not at issue in any other actions except ***Sanofi-Aventis U.S. LLC et al. v. Fresenius Kabi USA, LLC,C. A. No. 14-7869 (MAS)(LHG); Sanofi-Aventis, U.S. LLC, et al. v. Accord Healthcare, Inc., C. A. No. 14-8079 (MAS)(LHG); Sanofi-Aventis U.S. LLC et al. v. BPI Labs, LLC et al., C. A. No. 14-8081 (MAS)(LHG); Sanofi-Aventis U.S. LLC et al. v. Fresenius Kabi USA, LLC, C. A. No. 14-8082 (MAS)(LHG); Sanofi-Aventis U.S. LLC et al. v. Apotex Corp. et al., C. A. No. 15-0287 (MAS)(LHG); Sanofi-Aventis U.S. LLC et al. v. Breckenridge Pharmaceutical, Inc., C. A. No. 15-0289 (MAS)(LHG); Sanofi-Aventis U.S. LLC et al. v. Onco Therapies Limited, C. A. No. 15-0290 (MAS)(LHG); Sanofi-Aventis U.S. LLC et al. v. Actavis LLC et al., C. A. No. 15-0776 (MAS)(LHG); Sanofi-Aventis U.S. LLC et al. v. Breckenridge Pharmaceutical, Inc., C.A. No. 15-1836 (MAS)(LHG); Sanofi-Aventis U.S. LLC et al. v. Apotex Corp. et al., C.A. No. 15-1835 (MAS)(LHG).***

__/s/ Eric I. Abraham_____
Eric. I. Abraham

Dated: March 20, 2015

CERTIFICATE OF SERVICE

The undersigned certifies and states that a true and accurate copy of the foregoing ***Defendants Apotex Corp, and Apotex Inc.'s Answer, Affirmative Defenses, and Counterclaims,*** was served on the counsel for Plaintiffs by electronic mail on March 20, 2015:

Liza M. Walsh, Esq.
Katelyn O'Reilly
CONNELL FOLEY LLP
85 Livingston Avenue
Roseland, New Jersey 07068-1765
(973) 535-0500
koreilly@connellfoley.com
lwalsh@connellfoley.com

William E. Solander
Jason A. Leonard
FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, NY 10104
(212) 218-2100
Jleanard@fchs.com

/s/ Eric I. Abraham
Eric I. Abraham